



OAML input on the CSMLS Application for the inclusion of the profession of Medical Laboratory Assistant (MLA) in the CMA conjoint accreditation process

The Ontario Association of Medical Laboratories represents all but one private laboratory in Ontario. Our members provide over 98% of the community laboratory testing which is just less than 50% of all diagnostic testing in the province. The remaining testing is performed in hospital and public health laboratories.

We thank you for the opportunity to provide feedback on the application by CSMLS for CMA Conjoint Accreditation of the Medical Laboratory Assistant training programs. Our response is in two sections.

The first section will provide an overview in three areas:

1. An overview of the systems and processes in place in laboratories to ensure high quality laboratory operations and test results
2. A discussion of the current training programs and laboratories' expectations of individual's seeking employment as an MLA
3. A discussion of whether an MLA is a health professional

An overview in these areas provides the context within which we discuss our specific concerns with the CSMLS application.

The second section deals with our overall concern with the specifics in the application namely that the conclusions are drawn with inadequate or no supporting evidence leaving the reader to draw incorrect conclusions that have not been clearly established, namely;

- a. That MLAs are the primary source of pre-analytical errors
- b. That there is a significant risk of harm to patients from MLA activities
- c. That there is a relationship between institutional MLA training programs and reduction in laboratory errors

Other concerns are also identified. We conclude that we are not able to support the application for the following reasons:

1. The case has not been made that pre-analytical errors will be reduced by establishing national standards for MLA training programs.
2. Inadequate recognition has been given to the evidence that the application of quality management principles in laboratories and hospitals have proven successful in reducing

analytical errors in the laboratory and medical errors in hospitals. One of the keys to this success is a shift in focus from the individual to building quality by focusing on improving processes and system.

3. Inadequate recognition has been given to the existence of laboratory accreditation programs with required quality management systems, Colleges of Physicians and Surgeons whose members include laboratory physicians, legislative and regulatory requirements, and licensing and inspection programs all of which contribute to helping ensure the quality of laboratory operations.

Quality in laboratories

Laboratories value highly the quality of the work they do and continually strive to ensure that errors throughout the laboratory process are minimized and patient safety is maximized. The Medical Director of the laboratory has overall responsibility and accountability for the quality of the laboratory operation, which includes all three stages of the diagnostic process (pre-analytical, analytical, and post-analytical). Regardless of the academic or professional training, certification, or prior work experience, internal orientation and training in the organizational policies and procedures is provided to employees. Policies as well as extensive detailed standard operation procedures, which are reviewed on an ongoing basis by the professional team, provide the MLA with the direction they must follow to ensure the quality standards are met. Laboratories in Ontario are accredited through the Quality Management Program for Laboratory Services (QMP-LS). Its accreditation is based on the requirements in ISO -15189 Medical Laboratories – Particular Requirements for Quality and Competence. Laboratory policies and procedures are based on nationally and internationally accepted standards of laboratory practise from the Clinical Laboratory Standards Institute (CLSI), formerly NCCLS. These standards cover pre-analytical, analytical and post analytical areas of testing. They also include discipline specific areas, phlebotomy, and safety practises in the laboratory. The current accepted methodology to address quality issues and reduce errors, in the health care sector and industry in general is to focus on system, process and design changes and not on individual employees when error reduction is desired.

Current training program

The community laboratory sector is not dissatisfied with the quality of students graduating from the approved training programs in the province. In Ontario private schools must be approved by the Ontario Society of Medical Laboratory Technologists as a precondition for the Ministry of Colleges Training and Universities to approve their Medical Laboratory Assistant/Technician program. The approval process includes a detailed review of all aspects of the program including curriculum, faculty, equipment and clinical placements as well as an onsite visit. Our member laboratories which provide clinical placements as part of the schools' program provide feedback to the schools on an ongoing basis. This feedback includes the laboratory's recommendations for curriculum changes to help the students be more prepared for employment in a laboratory or specimen collection centre.

Laboratories expect students to graduate with basic English and math skills, and a basic understanding of the laboratory work environment: MLAs should understand the scope of their

role and that of the health professionals working in the laboratory. Graduation from these schools should also provide them with strong data entry skills, familiarity with a limited number of basic pieces of laboratory equipment, laboratory processes and disciplines, basic safety information and initial phlebotomy experience. The student should have realistic expectations of what it will be like to work in a laboratory as distinct from other types of work environments. If MLAs come to the laboratory with this background knowledge, this will speed their learning curve; however, labs do not depend on this type of background. The critical portion of MLA training is on the job training provided by the employer. It is the responsibility of the lab, not the training schools to ensure employees' competency and knowledge of organization specific policies and procedures.

The MLA as a professional

The professional team in the laboratory is composed of:

- Medical director
- Laboratory supervisor
- Laboratory scientists
- Laboratory managers
- Medical laboratory technologists

As pointed out above the Medical Director has overall responsibility and accountability for the quality of the laboratory operation. Because all employees are expected to act in a professional manner does not mean that all employees are health professionals. Medical laboratory assistants are important support personnel on our team but we do not classify them as health professionals. For the same reason it would be inappropriate to describe ward clerks in a hospital, ECG technicians, and individuals in support roles to medical radiation technologists or radiation therapists as health professionals. Dental assistants, unlike dental hygienists are not considered health professionals even though they do provide important support to dentists.

Although phlebotomy is a controlled act, the Regulated Health Professions Act (RHPA) does provide an exemption for persons employed by a laboratory or specimen collection centre licensed under the Laboratory and Specimen Collection Centre Licensing Act (LSCCLA). The LSCCLA specifies that "no person shall be employed by the owner or operator of a specimen collection centre for the purpose of taking specimens from the human body unless a legally qualified medical practitioner has certified in writing ...that the person has competence in the technique of taking and collecting specimens from the human body". This reinforces the obligation of the employer through the medical director to ensure the quality of all aspects of the laboratory operation including venipuncture.

This section will discuss the concerns we have with specific elements of the submission. We have reviewed the three references provided to us that were included in the application submitted to the CMA. Upon reviewing these references which were provided to support the statements in the application we concluded that certain claims or statements in the submission may be open to question.

Conclusions drawn with inadequate or no supporting evidence

There has been a strong focus in the last number of years on evidence-based practice in the health sector. We have taken a more than cursory review of the three references which were submitted with this application.^{1, 2, and 3.} We found two basic problems with the references. First, we could not find any Canadian data cited. In fact a QMP-LS presentation provided with the CSMLS application states that no Canadian data are available.⁴ Second, we were able to identify several areas where conclusions are not supported in the references provided.

It is arguable that because of the dramatic differences in the health care funding, delivery systems, and regulatory frameworks among Canada, United States and Europe, the conclusions drawn from studies in other countries may not be applicable in Canada. On that basis alone, one must be extremely cautious about what conclusions from studies in other jurisdictions are considered valid and transferable here. We are concerned about the applicability of these data in the Canadian context.

In addition to those concerns, we have also identified several examples of statements or conclusions which we do not believe are supported by the studies provided in the application:

The medical literature indicates that pre-analytical errors account for 85% of the errors in diagnostic testing.

This statement in the submission is not supported by the evidence. The article by Pai referencing Bonini states “the pre-analytical AND post-analytical phases are the greatest contributor to laboratory mistakes and form between 68-87% of errors”. Although the data does not seem to be able to adequately differentiate between pre- and post-analytical errors, an undated handout provided by the CSMLS⁵ summarizes in chart form the total analytical error distribution, referencing studies by Plebani et al⁶ and Ross and Boone.⁷ (See Figure 1). These data seriously challenge the statement that 85% of errors are at the pre-analytical stage. Bonini speaks of the limitations of their review including the fact that most studies focus simply on analytical errors. He goes on to state that their literature search for the 8 years 1994-2001 “revealed large heterogeneity in study designs and the quality on this topic as well as relatively few available data and the lack of a shared definition of laboratory error”. More importantly he goes on to say that the literature on laboratory errors is scarce, attributable to the practical difficulty in reporting and measuring the number of errors and no universally acceptable definition of error. He concludes that there is a need for “implementation of a more rigorous methodology for error detection and classification and the adoption of proper technologies for error reduction. Clinical audits should be used to detect errors caused by organizational problems outside the laboratory.” Where detailed information was provided for the studies that were reviewed it was clear these data refer to hospital experiences in the U.K and U.S. The transferability of the data to the Ontario or Canadian scene is arguable. In addition many of the studies are 7-10 years old during which time there have been significant advancements in the application of quality programs in laboratories.

Figure 1: Total Analytical Error Distribution

Error Source	Ross & Boone ⁷	Plebani et al. ⁶
Pre-Analytical	46%	68%
Analytical	7%	13%
Post-Analytical	47%	19%

MLAs are the primary source of pre-analytical errors.

If not explicit, then certainly implicit in the application is the identification of the MLA as a significant contributor to pre-analytical errors. In Ontario about 45% of the testing is performed by community laboratories. Thirty per cent of these specimens are collected in physician offices and may be collected by the physicians himself/herself, a nurse or other staff person in the office. Very few MLAs work in physicians' offices. Approximately 55% of the testing volume in the province is performed in hospitals. There are a variety of persons who collect specimens in hospitals including nurses, residents, phlebotomists, MLTs and MLAs. We saw no evidence that points to the medical laboratory assistant as significant source of pre-analytical errors. Bonini ¹ indicates that it is possible, even probable that the most frequent pre-analytical errors are represented by an inappropriate choice of laboratory tests or panel of tests and the most post-analytical errors derive from inappropriate interpretation and utilization of laboratory results. Both of these activities fall within the scope of practice of Regulated Health Professionals and are not within the job responsibilities of the MLA.

Risk of harm to patients

Despite the extensive amount written on 'medical errors' there is a paucity of research on errors in laboratory medicine and, due to "the lack of a universally accepted definition of error and above all of 'allowable error rate', reduces the possibility of evaluating the impact of laboratory error on patient outcome" (Bonini) ¹. Most medical errors are likely system related and less attributable to individual negligence or malpractice. The key to reducing errors is to focus on improving the system (Lippi et al). It is undeniable that there is a risk of harm to patients associated with laboratory errors. With the lack of a shared definition of pre-and post analytical lab error (which to many include ordering the wrong test and misinterpreting the test result) and the lack of sufficient data quantifying the amount and cause of errors which result in serious risk to patient; there is no basis to conclude that the focus of any effort to reduce errors should be directed at the pre- employment training of the MLA. Lippi points out the lack of standardized procedures for specimen collection account for up to 93% of errors "highlights the imperative of good laboratory practice and compliance with accreditation standards which encompass adoption of strategies of error prevention and tracking whether corrective actions were actually successful in error reduction..." Overall, inappropriate specimen quality and quantity account for 60% of the pre-analytical errors (Lippi et al.) ³. They conclude that certification of phlebotomists preferably developed by the laboratory is an essential part of the process of standardization. In

Ontario this is accomplished by employer through the sign off by the Medical Director. Our experience has been that MLAs become proficient in phlebotomy only through practice with real patients in a supervised work situation. A limited number of draws on classmates do not provide the variety of experiences necessary to become confident and proficient in performing venipuncture.

There exists a relationship between education in a training program prior to employment and the reduction in pre-analytical errors

No evidence establishing a relationship between pre-analytical error rates and pre-employment training has been provided; however, one of the premises of the application is that having a national accreditation standard for MLA training will reduce the pre-analytical errors in laboratories and thus improve patient safety. Pai proposes four measures to be taken to reduce laboratory error:

1-Good communication is one of the most important means that we have at our disposal in our attempt to reduce error in the laboratory (E.g. Nurses are aware of specimen labelling requirements.)

2-Make reports clear – pathologists must strive to make their reports clear, concise and standardised

3-Unexpected results – from the clinician’s point of view, it is healthy practice to ask the pathologist to reconsider or re-evaluate a diagnosis when dealing with unexpected results

4- Keep abreast of advances in the field – hospitals often have doctors from various fields with different levels of understanding and at different levels of training.

Pai does not identify MLAs as a focus for reducing laboratory errors.

Lippi does recognize the importance of proper training and knowledge as factors that are essential for minimizing errors and improving the whole patient management process. This is accomplished through the internal training of employees in laboratory operating policies and procedures based on nationally and internationally recognized standards (ISO & CLSI) and on quality systems and processes within the laboratory.

Juxtaposing of wording leads reader to draw incorrect conclusion

The CSMLS when proposing a definition juxtaposes the words MLA and Profession and defines “*the MLA profession* as medical laboratory workers who...” It is arguable whether or not MLAs represent a “profession”. As explained above we do not believe this to be the case.

An objective approach to the question at hand would be stated differently for example, “MLAs are medical laboratory workers who...” The use of the phrase MLA profession in the definition inappropriately presupposes a conclusion which an analysis has yet to conclude.

In response to Criterion 1.3 the CSMLS states that the medical literature indicates that pre-analytical errors account for 85% of the errors in diagnostic testing and that qualified MLAs are a key factor in minimizing these errors. Statistics Canada estimates that there are approximately 22,800 MLAs in Canada. Without discussing the accuracy of the first statement, the juxtaposing of these two statements leaves the reader with the incorrect impression that there is a pervasive problem in Canada and leaves the reader to draw the incorrect conclusion that the vast majority

of pre-analytical errors are caused by MLAs, and furthermore this problem will be addressed by supporting this application. In addition no evidence has been provided establishing a relationship between pre-analytical error rates and pre-employment training.

We believe this presentation overstates the problem in a dramatic fashion and presents a position which is not valid based on the evidence submitted. We feel this is an unfair sleight on both the MLAs as well as quality programs in place in laboratories in the province and across Canada.

Incorrect facts/information

The CSMLS definition of MLAs as “medical workers who perform pre-analytical tasks under the direct supervision of a medical laboratory technologist” is not correct on two counts. Firstly MLAs may perform tasks at all three stages in the laboratory process: pre-analytical stage (entering patient information into a computer), analytical stage (loading specimens onto an analyzer), and post-analytical stage (filing reports). Secondly, MLAs work under direct supervision of MLTs until they are deemed competent in the performance of their tasks. After which they are still supervised but in an indirect manner. It should be pointed out that the RHPA provides an exemption allowing a person to perform the controlled act of phlebotomy if the person taking the blood sample is employed by a laboratory or specimen collection centre licensed under the Laboratory and Specimen Collection Centre Licensing Act. In such circumstances the medical director of the laboratory, must attest to the competence of the individual to perform phlebotomy in the work setting.

Other considerations for the review committee

- Consideration must be given by the committee to the basic question of what level of knowledge is expected of a graduating student prior to entering the workforce. Does the level of knowledge expected require establishing a national standard? Further, what training is provided by the employer to ensure competency before allowing the employee to assume full job responsibilities? Thirdly do other regulated health professionals have supervisory responsibilities over the employee? Without diminishing the value of national standards one has to be cautious of overenthusiastic application of this mechanism and applying it in situations and conditions in which it is not warranted. Medical laboratory **technology** is a regulated health profession and a national standard is appropriate for them. This is not the case for technicians. In this particular application one faces the risk of setting a precedent of establishing a national standard for support personnel to all health professionals. This may lead to similar applications from support personnel to other health professionals.
- MLAs are not self-employed and do not work as independent practitioners. They perform their functions with the oversight of other health professionals (some of which are themselves regulated health professions) as well as organizationally imposed policies and procedures, and under regulatory and mandatory quality system processes. We believe such oversight significantly reduces the risk of harm to patients by the activities of the MLA. A nationally accredited education program will in no way contribute to the reduction of whatever risk may be present.

- Laboratories operate in a highly regulated environment. Unless there is a well identified need with clear benefits to be had, imposing further requirements place unnecessary demands on the resources of the laboratory providers. This application has not adequately demonstrated that a need exists for accreditation of MLA training programs or that benefits will be achieved through accreditation.

Conclusions:

- 1. The OAML does not support the application to include medical laboratory technicians in the CMA conjoint accreditation process.**
- 2. We recognize medical laboratory technicians as important support persons to the laboratory team of health professionals but do not consider them to be health professionals.**
- 3. We believe the submission overstates the problem in a dramatic fashion and presents a position which is not valid based on the evidence submitted. There is insufficient evidence that MLAs are the primary source of pre-or post analytical errors and that there is any relationship between pre-employment training standards for MLAs and reduction in such errors. If there is a need to improve the pre-analytical stage of the laboratory process there are other ways to address this issue that have been shown to have an impact on error reduction.**
- 4. Inadequate recognition has been given to the evidence that reduction in analytical errors in the laboratory and medical errors in hospitals have been achieved by changes in systems and processes not by focussing on changing the individual.**
- 5. Inadequate recognition has been given to the existence of laboratory accreditation programs, regulatory requirements and licensing and inspection programs all of which contribute to helping ensure the quality of laboratory operations.**
- 6. Inadequate recognition has been given to the importance of employee training in laboratory specific systems, processes and standard operating procedures as mechanisms for ensuring quality laboratory operations.**
- 7. Inadequate recognition of the role of two other regulated health professionals providing oversight in laboratory operations: physicians and medical laboratory technologists.**

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